

## Irvine Biomedical Implements ePartnersMD

Microsoft Dynamics to Effect Healthy Growth  
in an FDA Compliant Environment

### Solution Brief

#### Customer Profile

Irvine Biomedical, Inc. provides medical products for improving the quality of life. IBI is located in Irvine, California, one of the world's premier centers of medical device technology. Thus, it has access to many of the top research and development, manufacturing, and marketing and sales organizations, both there and around the world.

#### Situation

Strong, rapid growth, combined with market potential and success, made it critical that the company implement a system that could support growth and manage compliance with stringent FDA regulations.

#### Solution

- > Microsoft Business Solutions Financial Management
- > Microsoft Business Solutions Manufacturing
- > Microsoft Business Solutions Supply Chain Management
- > Microsoft Business Solutions Great Plains

#### Business Benefits

- > Ease of use yields an empowered, motivated work force
- > Improved materials management control
- > Ability to manage a complex, demanding FDA-compliant environment
- > A solid basis for future growth and increasing complexity
- > Improved reporting capabilities
- > Improved forecasting and planning capabilities

#### Industry

Manufacturing

The mission of Irvine Biomedical Inc. (IBI) is serious, straight forward, and ambitious: to provide the best medical products for improving the quality of life. In pursuit of this goal, the Irvine, California-based medical device manufacturer has concentrated its efforts on catheter-related products for cardiovascular applications, with a major focus on electrophysiology — one of the fastest growing segments in the dynamic cardiovascular arena.

Due to the success with which its products have been received, IBI has experienced strong and rapid growth. This combination of market potential and success made it imperative that the company implement a business solution that allowed them to effectively manage current growth while providing the capacity to scale for and manage future growth. Microsoft Business Solutions Great Plains provided that capacity while meeting IBI's rigorous FDA-compliance requirements.

#### Rapid Expansion Drives Need for New Solution

Because of the tremendous potential for new products in this market, IBI had a rapidly expanding product portfolio. By the middle of 2002, it was clear that IBI needed a new business solution to help them maintain and further the gains they were making in the highly competitive medical device market.



Microsoft Dynamics

Microsoft Business Solutions, Great Plains, Microsoft CRM, Solomon and Axapta are now part of the Microsoft Dynamics family.



## Putting the Whole Picture into Focus

“With the software we had in place, our manufacturing and purchasing modules did not interface with the accounting and financial modules, so neither side was seeing the whole picture of IBI,” says Brett L. Scott, Chief Financial Officer at IBI. “We had to jury-rig the connection; so for example, in determining order points for materials going forward, there wasn’t any forecasting taking place, save for notes and sketches on backs of envelopes, etc.”

Scott, who had just come to IBI to help steward the privately owned concern to its next level of growth, knew that this status quo wouldn’t do. He took on a driving role in finding the next generation business solution for the company.

The medical device industry is heavily regulated by the Federal Drug Administration (FDA), which requires detailed process and product documentation (e.g. serialized inventory, lot tracking to the component level, etc.). “I’m always sensitive when looking at software and systems, as to whether they’re capable of handling the needs of a medical device company,” says Scott, who has served in executive capacities in the industry for over 15 years.

## Solution

Sometime earlier, Scott had attended a seminar given by ePartners®, a leading Microsoft® partner. At that session, Scott had seen a software package presented that he felt could handle the demanding requirements of a medical device manufacturer. He contacted ePartners to invite their representatives to detail the advantages of Microsoft Business Solutions – Great Plains.

IBI had recently signed a large contract with a major medical products distributor that increased demand significantly, and they needed a way to manage that demand and to scale effectively to the middle-market phase of enterprise development.

“IBI was a relatively small company experiencing significant growth,” says Graham O’Brien, project manager at ePartners’ Los Angeles office. “Microsoft Business Solutions was an ideal fit for IBI. It provided them an affordable, easy-to-implement, easy-to-operate, scalable solution that addressed and integrated their business process needs while supporting the tough regulatory requirements of their industry.” After ePartners provided the proof of applicability for Microsoft Business Solutions to IBI, the software was purchased in late May 2002. Project implementation began the following month and went live January 1, 2003.

## Microsoft Business Solutions at IBI

“To support IBI’s regulatory compliance requirements, Microsoft Business Solutions tracks each and every item by lot number. Each item that comes into the IBI facility undergoes a quality control inspection that is recorded in the system. Customizations by ePartners enabled IBI to have signatures and sign-offs on each lot number that goes into a product as well as significant documentation around the work order,” notes O’Brien.

Of particular note is the ‘Work Traveler,’ a document that accompanies work in progress as it moves through production. In a typical manufacturing setting, a document of this type would be one or two pages. At IBI, it is a 20-page packet in a plastic seal, itemizing the step-by-step process of what needs to happen to build a product, with detailed references to standard operating procedures (SOPs) and FDA-regulated documentation.

## Certification Requirements

According to Bonnie Bishop, director of regulatory affairs and quality assurance at IBI, one of the biggest improvements enabled by Microsoft Business Solutions is in the area of certifications. With some shipments approaching a value of \$500,000 each, customer certifications are critical. “We have a number of important customers with very specific needs regarding the certification we provide them,” says Bishop. “Before implementing the new software, we had to manually generate these documents, typically many pages long, which were bundled into product shipments. Now the same customer can get needed documentation through automated processes in seconds via Microsoft Business Solutions. What used to take an hour or more is now done in a blink.” “Scott notes that in addition to greater speed and less labor, accuracy is also significantly improved. Microsoft Business Solutions assigns lots for each shipment, then certifies according to customer requirements for validating signatures. “Before, if there was a mistake or an omission on a certification, all certifications would have to be redone,” adds Bishop. With the automated documentation, missing or errant information is rapidly and easily identified — and quickly corrected on the system. Prior to this, finding lost data often required long and costly manual searches.

The comprehensive lot tracking is a key feature. Microsoft Business Solutions helps IBI identify and track each customer and the lot the customer receives, and it provides a more rigorous system for verifying physical lots and relating them to shipments. “Importantly, the system also provides us a much better view of the build process,” says Bishop. “Previously, we knew that a work order was generated—but we didn’t know its current status. Now we do know, and this includes information about raw materials as well.”

### Business Benefits

#### Ease of Use Yields an Empowered, Motivated Work Force

According to Scott, since implementing Microsoft Business Solutions, a positive trend has emerged—that of a motivated workforce learning a great deal about how they can improve what they are doing, and improving the record keeping of the processes in which they are involved. “Before coming to IBI, I had been involved in another business solution implementation which was very difficult for personnel to understand,” Scott says. “The result was low productivity and high turnover after implementation. The Microsoft Business Solutions system is a night and day difference from my previous experience. Our people have grasped it quickly, and there isn’t a high level of frustration. This means greater productivity, greater workforce satisfaction, and high retention of valuable personnel. It benefits the company greatly at that important level.”

#### Improved Materials Management Control

Though the system has been in place for less than six months, Scott already sees hard business benefits accruing, particularly in the area of materials management. “Before, we were unsure if and when we were going to be short of inventory; or conversely, the inventory build up would creep up to the point where we had

to take drastic steps, renegotiate with vendors, and so on. Now our raw materials inventory is in better shape than it has ever been before.”

#### Building on the basics – a system to grow with –

Scott sees IBI at the beginning stages of leveraging the Microsoft Business Solutions functionality, having what he calls ‘the basics under our belts.’ “We can build, we can ship, we can account for what we’re building, we can collect the money, we can record that activity, we can get out financials, we can compare actual versus budget; but a lot of the value this system will provide is yet to come – in terms of really tightening the material requirements and getting benefits from our engineering and regulatory groups (e.g., having engineering change orders (ECOs) so that R&D and purchasing can see them in real time, and having regulatory personnel help with the change processes).”

#### Improving forecasting and planning –

Scott’s immediate focus is on improving forecasting and planning, a challenge he sees Microsoft Business Solutions as strongly supporting. “We’ve been able to help IBI purchase inventory with the plan in mind,” says O’Brien, and in the medical device industry that’s an essential capability. “By providing additional visibility into processes, from both an operations and P&L standpoint, we’re able to give IBI the whole, integrated picture and eliminate things like panic-based buying that come about from truncated views.”

And that is indeed improving the quality of life at IBI and other small to midsize companies coping with the challenges of effectively managing growth.

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